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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,382	02/19/2004	Hosheng Tu	GLAUKO.1C2C2	3584

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

WIEST, PHILIP R

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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03/31/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/782,382	Applicant(s) TU ET AL.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In the reply filed 1/10/08, applicant amended claims 1 and 2. Claims 1-3 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,544,249) in view of Lynch (6,827,700).

3. With respect to Claims 1 and 3, Yu et al. (hereafter Yu) discloses an implant comprising an outflow portion 12 sized and shaped to be received within Schlemm's canal of an eye, and an inflow portion 14 in fluid communication with the outflow portion, the inflow portion configured to be disposed in the anterior chamber of the eye (Column 2, Lines 59-62). An applicator 30 is configured to releasibly hold the implant and deliver said implant into the anterior chamber for implantation into eye tissue (see Figures 3-8). Yu, however, does not disclose that the inlet of the implant is disposed transversely to the outlet.

Lynch discloses an ocular shunt comprising a inflow portion disposed transversely to an outflow portion, wherein the inflow portion is located in the anterior chamber and the outflow portion is located in Schlemm's canal. This arrangement allows for the implant to be substantially fixed to the trabecular meshwork, eliminating the need for anchoring means, and allows the outflow portion to be oriented in the plane of Schlemm's canal (Column 10, Lines 11-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the ocular implant and applicator of Yu with the L-shaped orientation of Lynch in order to anchor the implant in position and allow the outflow portion to be oriented parallel to Schlemm's canal, allowing the implant to follow the natural shape of Schlemm's canal.

4. With respect to Claim 2, Yu discloses that the implant comprises a tube 32 that releasably holds at least part of the inflow portion of the implant.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (US 6,827,700) in view of Ritch et al. (US 5,092,837). Lynch discloses an ocular shunt implant comprising an outflow portion 25 sized and shaped to be received within Schlemm's canal, and an inflow portion 10 in fluid communication with the outflow portion 25, said inflow portion configured to be disposed in the anterior chamber of the eye (Column 1, Lines 20-27). The long axis of the inflow portion of the implant 10 is disposed at an angle (90 degrees or "L-shaped") to the outflow portion 25 (see Figures

1-4). Lynch, however, does not specifically disclose that the implant is inserted into the eye using an applicator.

Ritch et al. (hereafter Ritch) discloses an ocular implant that is inserted into the anterior chamber of the eye by a tubular applicator that releasably holds the implant for implantation into the eye tissue. The use of a tubular applicator allows for implants to be inserted into the eye with a single instrument, rather than forming several large incisions on the outer surface of the eye. Furthermore, the use of tubular applicators is well established in the art of glaucoma treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the ocular implant of Lynch with the insertion method of Ritch in order to provide a means for inserting an implant on the inner surface of the eye while puncturing as little tissue as possible.

Furthermore, when the inflow portion of the implant of Lynch is releasably held by an applicator, the outflow portion of the implant will be disposed at a 90-degree angle.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, and 5 of copending Application No. 11/121584 (PGPubs 2005/0192527). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a combination of an implant and an actuator for introducing the implant into the eye.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of Patent No. 6,780,164 in view of Lynch et al. ('700).

Claim 5 of the patent discloses an instrument for delivering implants into the body, wherein the implants are held within the body of the instrument. While the application '213 claim 5 discloses the invention substantially as claimed, it fails to disclose specifically that the implant is substantially L-shaped. Lynch et al. discloses a glaucoma shunt (i.e. implant) that may be substantially L-shaped (see figures 1-5). At

the time of the invention, it would have been an obvious design choice to modify the shape of the implant of the copending claim 5 to be substantially L-shaped as taught by Lynch to provide greater patency of the implant when disposed in the body would be within the level of ordinary skill in the art.

Response to Arguments

9. Applicant's arguments with respect to claims 1-3 in view of Yu have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments with respect to the 103 rejection over Lynch in view of Ritch have been fully considered but they are not persuasive. Applicant argues that the filing date of the Lynch patent is later than the priority date of the instant application, and that the provisional application does not disclose everything in the Lynch application.

While the examiner concedes that Lynch's provisional application does not disclose every aspect of the formal application, it does disclose the use of a T-shaped implant that is similar to the claimed L-shaped implant but with an additional drainage arm. For this reason, Lynch clearly anticipates the use of an implant having the inflow portion disposed transversely to the outflow portion.

Additionally, applicant argues that the implant of Lynch could not possibly be used with the applicator of Ritch because Ritch does not disclose the use of the applicator with curved implants. This has not been found persuasive. The implant of

Ritch is not perfectly linear because the corners of the implant extend transversely (see figures 4A-4D). The Ritch applicator is *fully capable* of holding a variety of implants.

Regardless, it is the examiner's position that it would have been within the scope of one of ordinary skill in the art to modify the applicator of Ritch such that it is capable of holding and implanting a non-linear implant, and Lynch clearly anticipates the use of an L-shaped implant.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761